

ATTACHMENT 4**510(k) Summary**

The 510(k) Summary is submitted in accordance with 21 CFR Part 807.92

1. Submitter's Name: Guidant Corporation
Advanced Cardiovascular Systems, Inc.
2. Submitter's Address: 3200 Lakeside Drive
Santa Clara, CA 95054
3. Telephone: 408-845-3995
4. Fax: 408-845-3743
5. Contact Person: Margaret Anderson
6. Date Prepared: February 22, 2000
7. Device Trade Name: 5F Guiding Catheter
8. Device Common Name: Percutaneous Catheter
9. Device Classification: Class II per 21 CFR 870.1250
10. Predicate Device: ACS VIKING™ Guiding Catheter, 6F (K972484)
11. Device Description:

The 5F Guiding Catheter is available in a 5F diameter with a standard length of 100 cm, but may be produced in lengths from 40 to 160 cm. The 5F Guiding Catheter is available in varying tip shapes. The guiding catheter has a radiopaque shaft, which varies in stiffness at the distal end. The catheter has a radiopaque soft tip and is available with or without side holes.

12. Intended Use:

The guiding catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced into the vasculature.

13. Technological Characteristics:

Comparisons of the proposed and predicate devices show that the technological characteristics such as materials, performance characteristics, sterilization and packaging are identical or substantially equivalent to the currently marketed predicate device. The design modifications of the 5F Guiding Catheter compared to that of the predicate ACS VIKING™ 6F Guiding Catheter are the inner and outer diameter dimensions, the soft tip and the inner liner length.

14. Performance Data:

The results of the functional testing demonstrated that the 5F Guiding Catheter met the established acceptance criteria and performed in a manner equivalent to the predicate device. No new safety or effectiveness issues were raised during the testing program.

15. Conclusions

Since the 5F Guiding Catheter has the same intended use, materials, technological characteristics, performance properties, identical sterilization and packaging, and no new safety or effectiveness issues, the 5F Guiding Catheter may be considered substantially equivalent to the predicate ACS 6F VIKING™ Guiding Catheter.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 24 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Margaret Anderson
Regulatory Affairs
Guidant Corporation
Advanced Cardiovascular Systems, Inc.
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K000598
Trade Name: 5F Guiding Catheter
Regulatory Class: II (two)
Product Code: DQY
Dated: February 22, 2000
Received: February 23, 2000

Dear Ms. Anderson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

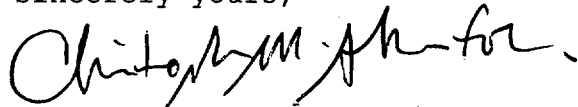
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chitoyan J. H. for.", is written over the typed name.

James E. Dillard III
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 2**Indications for Use Statement**

510(k) Number
(if known)

Device Name 5F Guiding Catheter

Indications for Use The guiding catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced into the vasculature.

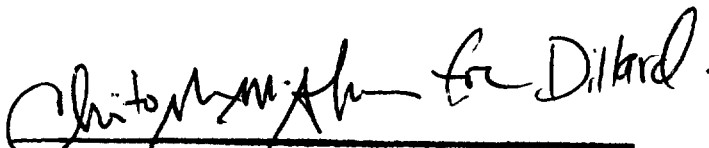
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IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000598